IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION _____ **This Document Relates To:** ***Ethicon Wave 8 Cases***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **U.S. District Judge**

Plaintiffs' Opposition to Defendants' Motion To Exclude The Opinions And Testimony Of Dr. Vladimir Iakovlev

Defendants Ethicon and Johnson & Johnson (hereinafter "Defendants") move to exclude general (but not specific) opinions and testimony of Dr. Vladimir Iakovlev from Wave 8 cases, arguing his opinions concerning polyester multifilament Mersilene are "unreliable and irrelevant" under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). *See* ECF No. 6875, MDL No. 2327 (hereinafter "Memorandum").

I. Dr. Iakovlev's Wave 8 General Opinions

In Wave 8, Dr. Vladimir Iakovlev has prepared a Supplemental Report for Issues Related To Mersilene Mesh. *See* Ex. B (Dr. Iakovlev's Wave 8 Supplemental Report). In the twelve-page Supplemental report, Dr. Iakovlev renders two general, limited opinions.

First, Dr. Iakovlev opines on "General Issues of Mesh Erosion/Exposure through Skin or Mucosa." *See* Ex. B. Dr. Iakovlev opines about primary and secondary mesh exposures, and how mesh design and material impact mesh erosion and exposure. *Id.* The general opinions Dr. Iakovlev offers about concerning mesh erosion/exposure are analogous to the testimony he previously has provided to the Court and to the jury, including in four separate pelvic mesh trials. And the Court has previously permitted Dr. Iakovlev to render opinions concerning polypropylene degredation. *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *68-69 (S.D. W. Va. July 8, 2014).

Second, relying on the scientific literature, Dr. Iakovlev opines on general issues of infection with multifilament meshes, including Mersilene, a polyester multifilament mesh. As in other cases, Dr. Iakovlev will opine on the tissue response to multifilament meshes (like polyester Mersilene) that is both reported in the medical and scientific literature, as well as what is observable through a pathology review. His general opinions in this Wave are consistent with testimony he has previously offered to this and other Courts. Dr. Iakovlev's opinions concerning multifilament Mersilene are well supported

with citations to the medical and scientific literature; and each is supported by Dr. Iakovlev's own experience as a clinical pathologist reviewing the explanted meshes of the Plaintiffs in this consolidated action and in his general practice.

Ethicon's arguments against Dr. Iakovlev go to the weight to be accorded his testimony, not whether the testimony is admissible under *Daubert*. Dr. Iakovlev's credentials make him qualified to offer the challenged opinions. Dr. Iakovlev employed reliable, well-established, "scientifically valid" techniques in reaching his circumscribed conclusions concerning polyester multifilament Mersilene. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 593(1993). Accordingly, Plaintiffs request the Court deny Defendants' motion to exclude Dr. Iakovlev's two limited general opinions in the Wave 8 cases.

II. Background And Dr. Iakovlev's Qualifications

Defendants open their attack with a blatant misrepresentation: "Prior to Wave 8, Dr. Iakovlev had *never* seen a Mersilene mesh." Memorandum at 2 (emphasis added). What Defendants *actually* asked was the first time Dr. Iakovlev had reviewed a Mersilene mesh for "legal purposes." *See* Ex. A at 9:21-24 ("Q. Was the mesh from Ms. Berden the first Mersilene that you reviewed for *legal* purposes? A. Yes, it is.") (emphasis added).

Dr. Iakovlev has prior clinical experience with multifilament polyester meshes (including Mersilene), and has reviewed all of them microscopically. *See* Ex. A at 8:20-9:14. Dr. Iakovlev's work and research, independent of this Wave, has included "polyester multifilament meshes" like Mersilene. Ex. A at 10:3-11:2. Dr. Iakovlev has seen many more polypropylene meshes than polyester meshes (like Mersilene) for a simple reason: basic market dynamics. Polypropylene is "over 90 percent of all meshes on the market now." Ex. A at 12:2-6.

The Court is familiar with Dr. Iakovlev's background and qualifications, which are presented in Dr. Iakovlev's Curriculum Vitae. *See* Exhibit B (Dr. Iakovlev's CV). As the Court has previously noted, Dr. Iakovlev is a highly qualified clinical pathologist. The Court has found him qualified to provide opinions similar to the limited opinions he proffers here in Wave 8. *See, e.g.*, *Edwards*, 2014 U.S. Dist. LEXIS 92316; *see also Eghnayem, et al. v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 712 (S.D. W. Va. 2014).

II. Standard on Federal Rule Of Evidence 702

Under Rule 702 of the Federal Rules of Evidence, expert testimony must satisfy a two-prong test: (1) the testimony must concern "scientific, technical, or other specialized knowledge," and (2) it must aid the jury to understand or resolve a fact at issue. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999), *citing Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993); Fed. R. Evid. 702. The first prong is aimed at excluding so-called "junk science." *Daubert*, 509 U.S. at 593. Courts should examine whether the reasoning or methodology underlying the expert's preferred opinions is reliable. *Westberry*, 178 F.3d at 257; *see also Daubert*, 509 U.S. at 593. The second prong relates to the testimony's relevance. Relevancy is satisfied where the expert's opinion is one that will be helpful to the jury. *Daubert*, 509 U.S. at 591. Rejection of expert testimony is to be the "exception rather than the rule." *United States v. Stanley*, 533 Fed. Appx. 325, 327 (4th Cir. 2013). Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the "traditional and appropriate" means of attacking expert testimony. *Daubert*, 509 U.S. at 596; *Cavallo*, 100 F.3d at 1158.

III. Argument

A. Dr. Iakovlev's Opinions Are Not Unreliable because They Take into Account Other Mesh Products

Defendants argue Dr. Iakovlev's opinions "draw heavily" from his work with monofilament polypropylene mesh, Memorandum at 5, as if experience with monofilament meshes is a disqualifying characteristic. Dr. Iakovlev explains that mesh design is significant in determining the likelihood of infection and erosion. Ex. B at 1-2; Ex. A at 101:6-102:24. Designs with smaller spaces, with interstices where bacteria can shelter, have historically been identified as being more prone to retain infection. Ex. B at 3; Ex. A at 17:12-19:8, 97:2-98:20, 101:6-102:24. It's the multifilament design of mesh that introduces additional risks of erosion and infection. Ex. A at 12:23-13:17, 15:22-19:8, 28:4-6, 90:3-25. His opinions focus on differences in infection and erosions rates by design—monofilament versus multifilament—on which Dr. Iakovlev has studied and published. Ex. A at 12:23-13:17, 35:3-13, 101:6-107:5. Dr. Iakovlev's experience with monofilament mesh is relevant to his opinions here.

Dr. Iakovlev, charges the defense, "makes no effort to reconcile" purported "inconsistencies" in the opinions he has given in the mesh litigations. Memorandum at 5. By opining with respect to the polypropylene mesh that the "location of implantation is a 'critical anatomic location' for mesh implantation in the pelvic floor," *id*. at 6, Dr. Iakovlev has somehow shown himself to be unreliable because implant location does not carry the same significance when giving opinions on multifilament versus monofilament mesh design and infection and erosion risks. *See id*. at 5-6. After decades of studying mesh design, a classification system was created. Ex. A at 30:13-31:13, 101:6-102:24. The Amid classification was "based on the risks of specific mesh designs" and the "main criteria for

classification were tissue ingrowth and infection." Ex. A at 30:13-31:5, 101:6-20. So "multifilament polypropylene" and "multifilament polyester" introduce the "same risks." Ex. A at 17:19-23. For this reason, Dr. Iakovlev explained, Mersilene's "main feature is multifilament; polyester is secondary." Ex. A at 66:21-67:13.

Defendants' location attack, which also concerns Dr. Iakovlev's consideration of different meshes, such as hernia mesh, Memorandum at 5-6, is particularly misguide because the Amid classification, under which Mersilene is a Class III multifilament, was developed in the context of hernia meshes. Ex. A at 30:13-31:5, 101:6-102:24; Ex. B at 4-8. Multifilament meshes "showed the same pattern" when introduced to vaginal and pelvic locations. Ex. A at 98:8-14. Both as a practicing pathologist and as a researcher, Dr. Iakovlev's observations about multifilament risks of infection and erosion were consistent with what was "described in the literature." Ex. A at 104:2-107:5. Defendants are mistaken in arguing Dr. Iakovlev lacks relevant experience and conducted a limited review of the literature, Mersilene in particular. Ex. A at 14:13-15:9, 22:5-23:16, 101:6-107:5; Ex. B at 1-12.

Defendants accuse Dr. Iakovlev of "rel[ying] on a motley and insufficient set of information" with which "to draw conclusions about Mersilene mesh." Memorandum at 7. As it primary example, the defense points to Dr. Iakovlev's reference to studies about hernia mesh. *Id.* This is a puzzling objection considering Mersilene's Instructions for Use says this "mesh may be used for the repair of hernia and other fascial deficiencies." Ex. C at 1. Moreover the Amid system for classifying different mesh designs, including Class III multifilament meshes such as Mersilene, was first developed in the context of hernia meshes. Ex. A at 30:13-31:5, 101:6-102:24; Ex. B at 4-8. The understanding of

multifilament meshes being "prone to infection … was established with hernia meshes." Ex. A at 98:1-11.

The defense fares no better criticizing Dr. Iakovlev's reference to ObTape, which is a multifilament polypropylene mesh. Memorandum at 7. But it's the multifilament design, whether the filaments are polyester, as in Mersilene, or polypropylene, as with ObTape, that "introduces additional risks, and the risks are erosion and especially infection." Ex. A at 13:7-13, 67:11-13, 96:13-17. For this reason, Mersilene's "main feature is multifilament; polyester is secondary." Ex. A at 66:21-67:13. Mersilene and ObTape are Amid Class III meshes, and the interstices between the filaments, which can shelter bacteria and impede the cellular traffic for fighting off bacteria, leading to infection. Ex. A at 17:12-18:8, 31:3-5, 102:5-104:1; Ex. B at 3-8. Either "multifilament polypropylene [or] multifilament polyester, they will introduce the exact[] same risks." Ex. A at 17:19-23.

References to silicon strips and ePTFE in Dr. Iakovlev's report demonstrates solid and microporous materials impede tissue ingrowth and have higher rates of erosion. Ex. A at 16:14-25. As the meshes "move from microporous to macroporous," the risk of erosion reduces, the proposition for which these products are referenced. Ex. A at 16:14-18:3. The Mersilene in the face (chin) reference is part of the historical background for when researches associated infections with Mersilene mesh. Ex. A at 99:22-100:23. Given these explanations, Dr. Iakovlev's information can hardly be viewed as "motley and insufficient." *See* Memorandum at 7.

Defendants place great weight on two decisions from outside this Circuit wherein certain opinions from Dr. Iakovlev were stricken. *See* Memorandum at 6-7 (discussing *Young v. Mentor Worldwide LLC*, 312 F. Supp. 3d 765 771 (E.D. Ark. 2018) and *Clinton*

v. Mentor Worldwide LLC, 2016 WL 7491861, at *12 (E.D. Mo. Dec. 30, 2016)). In *Clinton*, the court addressed opinions about ObTape, a polypropylene mesh, regarding degradation, which depended on a product review "not specific to ObTape and … formulated for expert testimony in other litigation." 2016 WL 7491861, at *12. Dr. Iakovlev even acknowledged that, unlike here, "only some of the general opinions in his expert report [were] actually applicable to ObTape." *Id.* These circumstances are much different from the facts surrounding Dr. Iakovlev's opinions in this case, which are developed through specific product research, specific research on multifilament and monofilament mesh, and Dr. Iakovlev's experience and education with mesh and the different types of mesh designs. Ex. A at 8:5-9:20, 35:6-15, 97:2-98:20, 101:6-107:5; Ex. B at 3-12.

Young also involved opinions regarding polypropylene degradation, *Young*, 312 F. Supp. 3d at 771, opinions that are not at issue in this case. Ex. B at 3-12. In contrast to this case, the *Young* opinions "cover[ed] all types of polypropylene mesh products," and Dr. Iakovlev testified that "complications from polypropylene mesh products are somewhat different depending on the device implanted." *Id.* Based on this testimony, the *Young* court concluded that ObTape-specific data was necessary. *Id.* As in *Clinton*, the court found significant that Dr. Iakovlev's general opinions were, unlike here, were formulated from work in other litigations and not specific to ObTape. *Id.* at 771-72. By contrast, Dr. Iakovlev's opinion are specific to Mersilene, specific to multifilament mesh, and specific to this case, Ex. B at 3-12, as even Defendants concede. Memorandum at 3 n.2.

B. Dr. Iakovlev's Opinions Regarding Mersilene Complications Are Reliable and Admissible

Defendants contend Dr. Iakovlev's opinions about Mersilene's risk of erosion and infection and the comparative risks between Mersilene and other meshes are unreliable and lack sufficient foundation. Memorandum at 8. The defense criticizes Dr. Iakovlev for acknowledging what his comprehensive review of the literature found—that "there is no large volume of literature on sacropexy meshes or Mersilene used for sacropexy." Ex. A at 32:18-33:2; *see* Memorandum at 8. The record is clear that Dr. Iakovlev did "review the literature involving Mersilene mesh" and was "searching for anything which was available" on Mersilene, "paying more attention to infection, because the case is about infection." Ex. A at 22:5-17. Dr. Iakovlev proceeded with an "open mind," while "focus[ing] for a specific case for Ms. Berden as well." Ex. A at 22:14-17. In the end, as Dr. Iakolev explained, "you can only go by what you have." Ex. A at 44:16-18.

The literature has shown that mesh constructs spaces in the mesh structure are more prone to retain infection and limit tissue growth. Ex. B at 3. Dr. Iakovlev has explained how this condition has been observed in multifilament sutures, hernia meshes, and pelvic floor meshes. Ex. B at 3-6, 8-11; Ex. A at 17:12-19:8, 97:2-98:20, 101:6-105:6. So it's the multifilament design of mesh that introduces additional risks of erosion and infection. Ex. A at 12:23-13:17, 15:22-19:8, 28:4-6, 35:3-13, 90:3-25, 101:6-107:5. And Dr. Iakovlev relies on literature that shows these results specifically occur in Mersilene as well. Ex. B at 8-11. Moreover, Dr. Iakovlev's medical practice experience comports with the literature, including with polyester multifilament mesh. Ex. A at 8:20-9:20, 102:25-104:15; *see also* Ex. A at 43:25-44:1 ("My opinions were formed based on many pieces of information.").

Defendants argue Dr. Iakovlev's opinions should be stricken because he does not "offer an overall rate of infection or erosion with Mersilene mesh." Memorandum at 8. But Dr. Iakovlev is opining on comparative infection and erosion risks between mesh designs, with particular emphasis on difference between Class III multifilament meshes, like Mersilene, and large pore (Class I) monofilament meshes. Ex. B at 3-11; Ex. A at 17:12-23, 18:6-19:8, 25:2-6, 26:4-14, 77:4-17, 97:2-98:14. The defense seizes on Dr. Iakovlev's statement that there may be some variability in Class I and Class III designs, Memorandum at 8, but completely ignores the rest of his answer, which affirms that "overall, class 3 meshes have higher risks of infection than class 1." Ex. A at 26:12-14. Defendants' criticism is misplaced, as is its critique that "Dr. Iakovlev's opinion attempts to extrapolate general mesh concepts to Mersilene without sufficient support." Memorandum at 9. The literature well supports his opinions as to the difference infection and erosion risks in multifilament and monofilament mesh. Ex. A at 101:6-107:5.

Defendants argue Dr. Iakovlev's opinions are unreliable because he cites few Mersilene articles and "no peer-reviewed study published in the last 12 years." Memorandum at 9. Dr. Iakovlev has been clear that he conducted a copious review of Mersilene literature and used what he found relevant after applying an "open mind." Ex. A at 22:5-17, 32:18-33:2, 44:16-18. Moreover, in his report, Dr. Iakovlev relies upon scores of articles as basis for his opinions. These articles describe the body's reaction to multifilament and monofilament mesh, as well as the risk of infection and erosion from these devices. Ex. A at 12:23-15:19; Ex. B at 2-11. Defendants' attack may be a topic for cross-examination but is does not to admissibility. *Edwards*, 2014 WL 3361923, at *1-2.

Nor does the absence of certain Nygaard articles from Dr. Iakovlev's list of supporting studies render his opinions unreliable as Defendants suggest. *See*

Memorandum at 9. When asked about a Nygaard article, Dr. Iakovlev remembered the name, and when he requested to the see the article and review, allowing him to refresh his memory and explain his reasoning, Defendants didn't have it. Ex. A at 63:3-12. This can hardly be a strike against Dr. Iakovlev considering Defendants weren't prepared to discuss the matter with him, and it is difficult to see how Dr. Iakovlev has failed to account, as Defendants argue, "for contrary scientific literature and instead selectively [chooses] his support from the scientific landscape" where the matter cannot even be discussed at deposition. *See* Ex. A at 63:3-12; Memorandum at 10 (quoting *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 520 (S.D. W. Va. 2014)).

Defendants fare no better attacking Dr. Iakovlev's "treatment of the literature he did consider." Memorandum at 10. Defendants point to testimony where Dr. Iakovlev mentions a study evaluating Marlex and a Mersilene study. *Id.* at 11. This is nitpicking. Marlex is identified in the name of the study, Ex. B at 8, 16, and when questioned about the study said "it would be useful for me to have it in front of me." Ex. A at 45:22-46:6. The article was not given. Ex. A at 45:22-46:10. Defendants had their slip of the tongue, and it was time to move on.

The defense also charges D. Iakovlev with "engag[ing] in unreliable statistical manipulation" to allegedly increase the Mersilene erosion rate. Memorandum at 11. But Defendants are simply unhappy with the detailed answer he provided for why, in his medical opinion, a study underestimated complication rates. Ex. A at 52:10-56:2. He explained that the "median followup of [the] entire study was shorter than the median time … until [the] appearance of erosions." Ex. A at 53:23-54:2. Dr. Iakovlev then explained why this was the case, concluding to a "reasonable degree of medical certainty" there was a "severe underestimation." Ex. A at 54:3-56:2. This is not manipulation, or

cherry-picking as Defendants contend. *See* Memorandum at 12. And it's unlike *Sanchez v. Boston Scientific Corporation*, where the expert "assume[d] the worst-case scenario" and gave the "benefit of the doubt to the patient." Memorandum at 12 (citing *Sanchez v. Boston Scientific Corp.*, 2014 WL 48551989, at *14 (S.D. W. Va. Sept. 29, 2014)). Here, Dr. Iakovlev has given no side the benefit of the doubt and instead has applied the requisite scrutiny. Defendants fail to show Dr. Iakovlev's opinions should be stricken.

C. Dr. Iakovlev's Opinions Using ObTape Are Reliable and Supported by the Evidence

Defendants contend Dr. Iakovlev is using the "ObTape device as a proxy" for Mersilene. Memorandum at 13. "Other than a shared characteristic of both being multifilament," the defense argues, "Dr. does nothing to explain how the devices are otherwise similar or how their differen[ces] … have no impact on erosion and infection rates." *Id.* But it is the multifilament design that makes ObTape so relevant to Dr. Iakovlev's opinions. The "main issue with multifilament meshes," explains Dr. Iakovlev, is mesh exposure and infection. Ex. A at 12:23-13:2. It is the multifilament design, whether the filaments are made of polyester, as with Mersilene, or polypropylene, as with ObTape, that "introduces additional risks, and the risks are erosion and especially infection." Ex. A at 13:7-13, 67:11-13, 96:13-17. That's why Mersilene's "main feature is multifilament; polyester is secondary." Ex. A at 66:21-67:13.

Both Mersilene and ObTape are Class III devices under the Amid mesh classification system, meaning both meshes are multifilament and have smaller spaces between the filaments, which is the critical component to the risk of infection. Ex. A at 17:12-18:8, 31:3-5, 102:5-10; Ex. B at 4-8. These smaller spaces "provide shelter for bacteria and less traffic" of the cellular bodies that fight bacteria. Ex. A at 102:15-104:1;

Ex. B at 3-4. So take "multifilament polypropylene versus multifilament polyester, [and] they will introduce the exact[] same risks." Ex. A at 17:19-23. This is the significance of the ObTape information regarding Dr. Iakovlev's opinions here. Ex. A at 97:2-99:7. ObTape is made of polypropylene, not polyester like Mersilene, but still evidences the higher rate of infection Dr. Iakovlev attributes to the multifilament design. Ex. A at 17:19-23, 18:17-8, 67:5-13, 97:2-99:7. Dr. Iakovlev has published a study comparing infection and erosion in ObTape, the lone polypropylene multifilament mesh, and polypropylene monofilament mesh. Ex. A at 38:4-10, 104:2-105:6. Dr. Iakovlev's study was "in line with [other] published studies showing class 3 [meshes] will have higher rates of infection." Ex. A at 104:16-105:3. Defendants simply misapprehend the relation of Obtape to Dr. Iakovlev's overall opinion in multifilament meshes. *See* Ex. A at 12:23-13:13, 67:11-13, 96:13-17, 101:6-107:5.

According to Defendants, "Dr. Iakovlev's own opinion that mesh design differences affect the risk" for erosion and infection highlights alleged shortcomings in his opinion. Memorandum at 13. Once more Defendants misconstrue Dr. Iakovlev's opinions. The relevant "design differences" are between monofilament and multifilament mesh. Ex. A at 17:12-23, 18:6-19:8, 25:2-6, 26:4-2, 77:4-17, 97:2-98:14. The mesh classification system, under which Mersilene and ObTape are both Class III, differentiated meshes "based on the risk of specific mesh designs," with multifilament meshes falling into the third category. Ex. A at 99:8-21, 101:6-20, 102:5-10. Defendants place great weight on mesh characteristics such as material composition and pore size, Memorandum at 13, but they are either taken into account under the Amid classification system (pore size) or do not impact Dr. Iakovlev's opinions regarding multifilament mesh and infection and

erosion (mesh materials). Ex. A at 12:23-13:17, 101:6-102:10. Nothing is "inconsistent" about Dr. Iakovlev's opinions, as Defendants baldly assert. Memorandum at 13.

In Defendants' view, Dr. Iakovlev is somehow unqualified to opinion on the risks and complications of multifilament mesh because he was unaware "if the erosion rate is higher or lower with ObTape compared to Mersilene mesh." Memorandum at 13. The defense misconstrues the testimony, which was an answer to a question about comparing erosion rate in abdominal sacral colpopexy. Ex. A at 99:8-15. And Dr. Iakovlev explained he "did not have those samples in [his] analysis. As far as [he] kn[ew], there was no comparison between them." Ex. A at 99:8-15. As for the importance between Mersilene and ObTape, Dr. Iakovlev further explained that both "belong[ed] to the same group of mesh by classification, class 3." Ex. A at 99:19-21.

The testimony shows Dr. Iakovlev is not using ObTape, as Defendants contend, as "simply an attempt to salvage his unreliable opinions on the risks of erosion and infection with Mersilene." Memorandum at 13. Instead ObTape's performance substantiates Dr. Iakovlev's opinions about Mersilene, as a multifilament mesh, being prone to infection by showing a multifilament mesh made of a different material also exhibits a greater risk of erosion and infection than a monofilament mesh made of the same material. The results of Dr. Iakovlev's study of ObTape and monofilament polypropylene mesh was "in line with all the[] published studies showing that class 3 [meshes] will have higher risks for infection."[1] Ex. A at 104:16-105:3.

D. Defendants Misconstrue Dr. Iakovlev's Reference to the Number of PubMed Articles Mentioning Mersilene

[1] Defendants contend "Dr. Iakovlev's same ObTape opinions were excluded by other courts in the ObTape litigation." Memorandum at 13. As shown above, *Young* and *Cinton* are not relevant to these opinions.

Defendants misconstrue the purpose for which Dr. Iakovlev includes a graph depicting numbers of PubMed articles mentioning Mersilene. Memorandum at 14-15. Dr. Iakovelev never uses the Mersilene graph, as Defendants contend, to "opine on the attitudes of surgeons" or the "development and usage of medical devices." *Id.* at 14. Instead Dr. Iakovlev incorporates the graph as an "easy to see" picture of trends of research interest in Mersilene and general device use. Ex. A at 35:16-37:1, 40:6-18. The graph shows that after Mersilene's introduction, "there's a spike, then enthusiasm [in the general literature] drops a little bit," reflecting a "natural evolution of things" through the 1990s when the mesh classification system was developed. Ex. A at 30:20-31:13, 36:6-37:1.

But Dr. Iakovlev is clear he is drawing "no conclusion" from the graph. Ex. A at 37:2-4. The graph is simply "one of the indicators" for identifying specific interest in multifilament mesh products, such as Mersilene. Ex. A at 38:18-24, 40:7-10. Other indicators of general interest in Mersilene and multifilament meshes, Dr. Iakovlev explains, include the fact that almost all newer vaginal meshes were monofilament designs and the only newer multifilament product for vaginal surgery was withdrawn from the market due to high complication rates. Ex. A at 37:8-38:24. Historic trends, as reflected in the PubMed data, were showing declining interest in Mersilene and multifilament mesh and increasing interest in monofilament mesh designs. Ex.A at 37:8-39:5.

Defendants argue Dr. Iakovlev should have verified the Corlan data he used for the graph by conducting independent searches on PubMed. Memorandum at 15. But Dr. Iakovlev is not opining on the exact number of Mersilene articles on PubMed, or on the exact publication dates of the articles, but instead on general trends in product interest.

Ex. A at 37:8-39:5, 40:7-41:8. Dr. Iakovlev has performed "multiple searches" of the Corlan data and confirms that the generated data "follow[] the historical events relatively well." Ex. A at 40:19-41:8. For example, Dr. Iakovlev has conducted searches in the Corlan data for polypropylene, vaginal mesh, hernia mesh, and hernia polypropylene. Ex. A at 35:16-36:19, 40:19-24; Ex. B at 12. The results from these searches identify "publication spikes after introduction of the device," demonstrate an increasing curve as the number of publications goes up, and show a "dip after [the] FDA warning" regarding vaginal mesh products. Ex. A at 36:4-18, 40:19-41:5. The testing of reliability is flexible, *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *2 (S.D. W. Va. July 8, 2014), and from specific searches related to his mesh work, Dr. Iakovlev has determined the Corlan data are reliable and accurate for his opinions. Ex. A at 40:19-41:8.

According to the defense, Dr. Iakovlev failed to heed the warning from the Corlan website that results "must always be interpreted carefully." Memorandum at 15. Defendants never explain, however, how Dr. Iakovlev allegedly "did no such checking found in the warning"; they instead rely on mere assertion. *See id.* In contrast, testimony shows Dr. Iakovlev has used the Corlan data on many occasions, has found the data to be accurate and comport with relevant historical events, has employed similar graphs in other mesh litigation reports, and has demonstrated the requisite expertise with mesh filaments to make these determinations. Ex. A at 35:10-37:1, 40:19-41:8, 101:10-107:5. Nor do Defendants advance their argument by contending "Dr. Iakovlev did nothing to verify the methodology" behind the Corlan data. Memorandum at 14. At issue is the reliability of the plotted Corlan data, Ex. B at 12, and Dr. Iakovlev has shown the data are accurate and reliable in identifying general trends of specific mesh products and specific mesh designs. Ex. A at 36:6-37:1, 40:6-41:8.

Defendants contend "[n]othing in [Dr. Iakovlev's] education, training, or research provides even a scintilla of qualification" for his PubMed opinions. Memorandum at 14. The defense once more misapprehends Dr. Iakovlev's use of this information. The graph of PubMed articles is one of several "indicators" Dr. Iakovev has identified that reflects declining research interest in Mersilene and general device use. Ex. A at 35:16-38:24, 40:6-18. Dr. Iakovlev has been focusing on mesh design and complications from different meshes, such as infection, since 2012. Ex. A at 12:23-13:17, 35:3-15, 101:10-107:5. He has examined the volume of mesh literature and release of new mesh products. Ex. A at 35:16-38:24, 40:19-41:8. For specific mesh-related literature, Dr. Iakovlev has observed patterns and trends in the publication volumes, and when the Corlan data is plotted in graph form, as Dr. Iakovlev has done here, "it follows the historical events relatively well." Ex. A at 35:16-37:1, 40:19-41:8. This testimony shows these opinions are reliable and helpful, which is all that is required. *See Maryland Cas.*, 137 F.3d at 783.

Finally, Defendants argue that "Dr. Iakovlev provides no basis for the conclusion that a reduction in the number [of Mersilene articles] over time demonstrates that knowledge of Mersilene's complications 'affected use and introduction of new multifilament designs.'" Memorandum at 15. Again, the PubMed information is one of several "indicators" Dr. Iakovev has identified, Ex. A at 35:16-38:24, 40:6-18, a fact Defendants appear to concede. *See* Memorandum at 15. Dr. Iakovlev never states, as Defendants assert, that specific "knowledge of Mersilene's complications" impacted use and introduction of new multifilament mesh products. *See id.* Rather, as Dr. Iakolev explains, it was the conclusion that the "multifilament mesh design was determined to have higher risks of infection, and the risk was … design specific." Ex. B at 11; *see id.* ("These conclusions [regarding a vaginal mesh] were in line with the earlier studies and

mesh classification based on the hernia surgical experience."); Ex. A at 12:23-13:17, 42:3-12, 66:16-67:13, 101:10-107:5. Dr. Iakovlev is well qualified to make his opinions given his personal experience and review of the relevant medical literature. Ex. A at 8:5-10:16, 12:23-15:9, 17:12-18:8, 22:5-17, 25:2-6, 28:4-9, 43:17-44:22, 84:1-9, 101:10-107:5; Ex. B at 8-11.

Defendants may dispute the evidentiary significance of Dr. Iakovlev's graph and how Dr. Iakovlev's uses this information, but these are topics for cross-examination and go to the weight of the opinions, not their admissibility. *Edwards*, 2014 WL 3361923, at *1-2. At this point, though, the Court may not decide which side is right. *Westberry*, 178 F.3d at 261.

IV. Conclusion

For the reasons stated herein, Plaintiff respectfully requests the Court deny Defendants' motion to exclude the general report of Dr. Vladimir Iakovlev in its entirety.

Date: October 25, 2018

Respectfully Submitted,

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Certificate Of Service

I hereby certify on October 25, 2018, I electronically filed Plaintiffs' Opposition to Defendants' Motion To Exclude The Opinions And Testimony Of Dr. Vladimir Iakovlev and Exhibits Annexed Hereto with the Clerk of the Court using the CM/ECF system, which will send notification of this Opposition and Annexed Exhibits to the CM/ECF participants registered to receive service in this MDL.

Respectfully Submitted,

/s/ Chris W. Cantrell

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